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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,411	01/16/2004	Elizabeth A. Gomez	03US7005	7477

23397 7590 05/18/2006

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EXAMINER	
FOSTER, CHRISTINE E	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/759,411	**Applicant(s)** GOMEZ ET AL.	
	Examiner Christine Foster	**Art Unit** 1641	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 02 May 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☒ They raise the issue of new matter (see NOTE below);
   (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *None*.
   Claim(s) objected to: *13*.
   Claim(s) rejected: *13-15 and 17-22*.
   Claim(s) withdrawn from consideration: *1-12*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

LONG V. LE 05/12/06
SUPERVISORY PATENT EXAMINER
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Continuation of 11. does NOT place the application in condition for allowance because:

The proposed amendments will not be entered because they raise new issues that would require further consideration and/or search; independent claim 13 now recites that the kit includes the limitation of a container for the interference blocking reagent, which was not previously a limitation of the claims. Furthermore, this limitation appears to represent new matter as no support could be found for a kit that includes a separate container for the interference blocking reagent (see for example the description of the claimed kit at [015]). The proposed amendments have also introduced the limitation that the sample be a "fluid" sample.

With respect to the rejection of claim 13 as being unpatentable over Newman et al. in view of Pourfarzaneh et al., Applicant argues that the "sample" referred to in the claimed invention is fundamentally different that that of Newman et al. in that the sample of the invention refers to fluid test or patient samples, i.e. serum/plasma (Applicant's response, p. 9) and/or that the sample is "non-divided" (Applicant's response, p. 10). This is not found persuasive because the claims fail to recite any limitations of the sample that distinguish it from that of the reference teaching. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, the proposed limitation of a "fluid" sample fails to distinguish the claimed invention from that of the references since Newman et al. also teaches fluid samples (see for example column 9, lines 19-53).

With respect to Applicant's argument that the sample of the claimed invention is evaluated so as to detect the presence and/or amount of intrinsic factor-specific antibody, while the sample of Newman et al. is evaluated for a different purpose and by different processes (see Applicant's response, p. 9-10), the Examiner notes that "detection of intrinsic factor-specific antibody" refers to the intended use of the kit and is not considered to be a limitation of the claims (see MPEP 2111.02). If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). See also Rowe v. Dror, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997). In the instant case the "sample" is not a limitation of the claimed kit per se, but refers to the intended use of the kit. Similarly, the detection of intrinsic factor-specific antibody refers to the intended use of the claimed kit. Because Newman et al. and Pourfarzaneh et al. teach all recited limitations of the kit components as claimed, such components would be capable of performing the intended use of the claimed invention with the intended sample type(s).

Applicant also argues that one skilled in the art attempting to solve the problem addressed by the present invention as claimed would not find motivation in Newman et al. to arrive at the claimed invention (Applicant's response, p. 10-11). This is not found persuasive because the reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem (see MPEP 2144). While there must be motivation to make the claimed invention, there is no requirement that the prior art provide the same reason as the applicant to make the claimed invention. In the instant case, the Examiner maintains that it would have been obvious to one of ordinary skill in the art to employ the anti-vitamin B12 monoclonal antibodies taught by Pourfarzaneh in place of the dextran-coated charcoal of Newman et al. in order to remove free vitamin B12 from samples, which is the same purpose for which the charcoal is used in Newman et al., and particularly in light of the well-known specificity of monoclonal antibodies. Applicant's argument (p. 11) that Pourfarzaneh teaches physical removal of all of the labeled bound complex from solution, which would obliterate the utility of the claimed invention, is not found persuasive. The Pourfarzaneh reference has been relied upon for its teaching of anti-vitamin B12 monoclonal antibodies, which is the same reagent recited in claim 18 (see also the previous Office action at p. 4-5 and 7-8). Similarly, Applicant further argues that Pourfarzaneh discloses solid phase binders, which cannot be used according to the claimed invention since they negatively impact immunoassays (p. 11). The Examiner fails to see the scientific merit in the argument, particularly as claim 13 recites a "solid phase binder" in the form of a specific binding pair member that is bound to a solid phase. Applicant further argues that Pourfarzaneh et al. teaches "physical deletion" while the claimed invention teaches "functional deletion" via the interference blocking reagent (p. 12). This argument is not found persuasive because such a feature of "functional deletion" is not recited in the claims and furthermore, appears to refer to the intended use of the claimed invention. Because Newman et al. and Pourfarzaneh et al. teach all recited limitations of the kit components, including the feature of an interference blocking reagent that is a monoclonal vitamin B12-specific antibody as claimed, the kit would be capable of performing the intended use(s) of the claimed invention, such as "functional deletion".